

Senegal, Egypt, Morocco, Algeria and Tunisia) are contributing # 80% of the pharma market in Africa. Despite maintaining regional offices within Africa, many major Pharma and device manufacturers frequently overlook the continent when sponsoring clinical studies. Cultural barriers, political upheaval and uneven infrastructure are certainly causes for the lack of interest. But Africa offers tremendous expertise and opportunity for drug and device companies looking for cost-effective study sites and appropriate patient drug market populations. Currently more than 45% of the whole continent's clinical trials are being conducted in South Africa and hence the need for the next generation clinical trial destination for a drug and device manufacturers. These companies can also consider technology transfer by partnering with local drug manufacturers and research centers to diversify their business portfolio. **CONCLUSIONS:** Africa presents real opportunities that should encourage many pharmaceutical companies to really engage in innovative clinical research programs in a win-win approach.

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MARKET ANALYSIS IN REGARD TO BIOLOGICALLY ACTIVE SUPPLEMENTS AND MEDICINES IN ARMENIA

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OBJECTIVES: Although, whether biologically active supplements (BAS) are medicines or not is still debatable, BAS keep making their way to the customer basically through pharmacies. A worldwide tendency toward “greener” choices when purchasing health status modifiers (HSM) is well documented. Current endeavor studies the pharmaceutical market situation (PMS) in Armenia (2009 to 2013) in regard to growth trends both in US dollars turnover (USDT) and number of packs sold (NPS) of BAS versus medicines, stratified by five leading diseases (LD). **METHODS:** Statistical data on morbidity and mortality from the MOH RA were used to identify the leading five disease groups in newly identified cases. Further, statistical data on pharmaceutical market from “Pharmexpert” Marketing Research Centre (analysis of wholesale sales volumes to the retail drug stores) were investigated to identify growth rate (GR) trends of interest. **RESULTS:** A PMS analysis has shown 11.92% and 6.65% of GR (medicines and BAS combined) in USDT and NPS respectively. For medicines alone the results were: 11.56% and 6.23% GR in USDT and NPS respectively. As for BAS, USDT and NPS, the figures were 21.48% and 15.36% of GR respectively. A further stratification by five LM has shown the highest GR in medicines used for treatment of Uro-Genital diseases (13.24% and 10.01% for USDT and NPS respectively), whereas in BAS the highest GR was in the Cardio-Vascular group (63.84% and 92.82% for USDT and NPS respectively). **CONCLUSIONS:** The results of the study go in line with the worldwide trends in shifting whenever possible, from medicines to using HSM of natural origin, of which BAS are a major part. The study does not claim to identify the underlying compound factors influencing such a tendency. However, the reality at had compels for studying the levels of BAS administration and use literacy among both HSM prescribers and consumers.

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IMPACT OF 2011 GERMAN HEALTH CARE REFORM ON PRICES

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OBJECTIVES: This study seeks to evaluate the incremental benefit scores granted to new medicines under the 2011 AMNOG reform in Germany, and if there is a correlation between that score and the extent of price reduction after negotiation with the statutory health insurance fund. **METHODS:** Resolutions issued by the G-BA related to all drugs which achieved the early benefit assessment process between January 2011 and June 2014 were reviewed to determine whether the drugs were deemed to bring an added benefit. Under AMNOG, an added therapeutic benefit score is granted to medicines according to 6 categories (major, considerable, minor, non-quantifiable, no or less added benefit versus the comparator). As part of the study, IHS created an overall quantitative innovation score for each product, based on any and all qualitative ratings granted by the G-BA in each patient subgroup. The score ranged from 0 (no added benefit proven) to 4 (major added benefit) and was weighted against each patient population. An average price reduction per innovation score range was then calculated. **RESULTS:** Out of the 76 drugs assessed in the study, a total of 44 were deemed to bring an added benefit over the appropriate comparator by the G-BA, of which 34 had achieved price negotiation as of end of May 2014. These ratings translated into an average innovation score of 1.77, and were subject to price cuts averaging 21.7%. **CONCLUSIONS:** Our analysis highlights that innovative medicines can be subject to significant price cuts in Germany. No correlation between the innovation score and subsequent price cuts could be derived, as many other factors, including the initial price difference between the new medicine and the comparator, enter into account as part of the price negotiations.

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REAL WORLD DATA (RWD) AT T=4 IN THE NETHERLANDS

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OBJECTIVES: If the cost-effectiveness and appropriate use of a drug in the Netherlands cannot yet be determined during the initial reimbursement assessment (T=0), this will be done at the re-evaluation 4 years later (T=4) using RWD. Outcome research is an essential part of the re-evaluation of conditionally reimbursed drugs. The objective was to assess the reasons for accepting or rejecting outcome research results to confirm cost-effectiveness and appropriate use of a drug at T=4. **METHODS:** The website of Zorginstituut Nederland (ZiNL) was searched for re-evaluations of drugs published between January 2006 and May 2014. ZiNL's assessments of the outcome research were compared. **RESULTS:** ZiNL published the outcome research results for four drugs. The outcome research results for agalsidase alfa & beta were accepted for demonstrating cost-effectiveness and appropriate use in Fabry's disease. The T=4 results for omalizumab for

the treatment of asthma were not accepted due to comments about population and model input, lack of statistical calculations and size of the incremental effects. Ranibizumab's results for age-related macular degeneration were not accepted because of a wrong comparator, lack of long term data, assumptions on risks and mortality, and uncertainties around health care costs and ICER sensitivity. Finally, ZiNL considered the appropriate use of alglucosidase alfa for Pompe's disease to be unsubstantiated because of the population choice for the ICER calculation and the use of a higher dose than the registered dose which was not supported by scientific data. The outcome results of alglucosidase alfa for cost-effectiveness were accepted, however. **CONCLUSIONS:** Although at T=0 ZiNL provided feedback regarding the design of the outcome research study, most of ZiNL's comments were on the final methodology used. The outcome research studies were considered to be of mixed quality and the results could often not substantiate the claim of cost-effectiveness and appropriate use.

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OPPORTUNITY COSTS OF IMPLEMENTING NICE DECISIONS IN NHS WALES

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OBJECTIVES: In the UK, when a technology is recommended by the National Institute for Health and Care Excellence (NICE), the NHS is mandated to provide the funding to accommodate it within three months. Explicit in NICE's approach to health technology assessment (HTA) is the assumption that the approval of a new, cost-increasing technology will result in the displacement of an existing, less cost-effective health care programme from elsewhere in the NHS. The objective of this study is to identify the actual opportunity costs of specific NICE decisions by documenting how in practice local commissioners in Wales accommodated financial shocks arising from technology appraisals (TAs). **METHODS:** Interviews were conducted with Finance and Medical Directors from all seven Local Health Boards (LHBs) in NHS Wales. These interviews covered prioritisation processes, as well as methods of financing NICE TAs and other financial “shocks” at each LHB. We then undertook a systematic identification of themes and topics from the information recorded. **RESULTS:** The financial impact of NICE TAs is generally planned for in advance and the majority of LHBs have contingency funds available for this purpose. Efficiency savings (defined as reductions in costs with no assumed reductions in quality) were a major source of funds for all cost pressures. Service displacements were not linkable to particular TAs and there appears to be a general lack of explicit prioritisation activities. The Welsh Government has, on occasion, acted as the funder of last resort. **CONCLUSIONS:** The assumption that newly recommended technologies will displace existing NHS services does not appear to hold true in practice. As the additional cost pressures represented by new NICE TAs are likely to be accommodated by greater efficiency and increased expenditure, the true opportunity cost of HTA decisions is extremely difficult to quantify and may even lie outside the NHS.

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FUNDING INTEGRATED HEALTH CARE SERVICES

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OBJECTIVES: Western countries health care systems face growing challenges dealing with disability and death due to chronic diseases. Coordination of health care services has become unavoidable. Our objective was to identify the Integrated Health Services (IHS) in the major health care markets and understand the funding process. **METHODS:** IHS provided in Europe, North America and Asia were identified through a literature review. Future perspectives were based on country policy and observed trends. **RESULTS:** All studied countries developed IHS such as disease management, case management and telemonitoring services, with the United States (US) being the major market. However, levels of implementation, funding processes and stakeholders involved vary highly between different countries. Funding processes such as fee for services and capitation are widely used in all studied countries and Payment for performance (P4P), bundled payment and diagnosis-related group (DRG) for outpatient are in progress, used mainly in the US, and to a much lower extent in the United Kingdom (UK) and Germany. Multiple IHS exists in France, though inappropriate incentives hinder their development. In the US, under the Affordable Care Act, Accountable Care Organisations (ACOs) are testing a range of payment models (capitation, one-sided/two-sided shared saving fee-for-service, bundled/episode payments and P4P). **CONCLUSIONS:** IHS have become ubiquitous in all health organisations. All countries studied are expected to develop more IHS based on P4P schemes. The P4P of ACOs represents the ultimate gold mine for the development of paid health care services. Even if this concept is still in progress it will be leading this market. This will also change dramatically the way pharmaceutical companies will do business. Drugs will have to be integrated in a more complex selling process driven by medium to long term outcome impact. The management of confounding factors on outcomes is critical and represents the challenge for ACOs.

PHP111

ACCEPTANCE OF TELEMONITORING BY HEALTH CARE PROFESSIONALS IN GERMANY: A QUESTION OF FINANCIAL CONDITIONS

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OBJECTIVES: The comprehensive implementation of telemedical applications still lags behind expectations in Germany. One of the main barriers to innovation is a lack of both a willingness to adapt and user's acceptance. Processes of adoption and acceptance are characterized by a network of different factors which influence attitude and behavior which differ in severity depending on each user group. One key factor for accepting and adopting an innovation is the economic framework. We therefore examined the influence of economic factors influencing the